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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF:

YESOOK KIM

Examiner: E. White

Art Unit: 1623

SERIAL NO.: **08/850,353**

FILED: **MAY 2, 1997**

FOR: **METHOD OF SELECTING A SALT FOR
MAKING AN INCLUSION COMPLEX**

I hereby certify that this correspondence
is being deposited with the United States
Postal Service as First Class Mail in an
envelope addressed to: Assistant Commissioner
for Patents, Washington, D.C. 20231 on

this 22nd day of December 20 00

Assistant Commissioner for Patents
Washington, D.C. 20231

By *[Signature]*

Sir:

Response To Non-Final Office Action

This is in response to the non-Final Office Action dated May 22, 2002 in the above-identified application, the term for response having been extended three (3) months by including the appropriate fee and petition herewith. In response to the Office Action, reconsideration is respectfully requested in view of the following comments and traversal.

As a preliminary matter, the Examiner's attention is directed to the Information Disclosure Statement submitted herewith.

In response to paragraphs 1 through 4 of the Office Action, Applicants elect to reply to the new ground of rejection.

Claims 1 through 3 are in the application. All three claims stand rejected as being indefinite, the Examiner having commented as follows:

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The preamble of the claims fail to correspond in scope with that which applicants regard as the invention because the claims are limited to the determination of the solubility of salts of compounds and comparing each measured solubility with a target solubility. There is no procedure that involve locating one or more salts of a compound in the body of the claim. It is not clear from the language used in the claims what other technique or procedure

applicants are referring to in order to locate one or more salts of a compound other than determining the solubility of a series of salts.

The preamble of Claims 1 and 2 also fail to correspond with the claimed language disclosed in Claims 1 and 2 because the only substantial step disclosed in the claims involves determining the solubility of the salts.

It is suggested that the claims be amended to read as:

-- A method of determining the solubility of one or more salts of a compound in cyclodextrin, said salts having a solubility in a cyclodextrin equal to or greater than a desired target solubility... -- for Claim 1 (for example). [Pages 2-3 of the Office Action]

Thus, the only rejection outstanding against claims 1-3 is the indefiniteness rejection expressed above. Before addressing the merits, Applicants believe it would be useful to discuss the legal requirements of definiteness. If those skilled in the art would have no difficulty understanding the subject matter intended, that is all that the second paragraph of §112 requires. The Patent Act "requires only reasonable precision in delineating the bounds of the claimed invention." United States v. Teletronics, Inc., 8 USPQ2d 1217 (fed. Cir. 1988). Also,

The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification... If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more.

See Miles Laboratories Inc. v. Shannon Inc., 27 USPQ2d 1123 (Fed. Cir. 1993), at page 1126. Further, an Applicant's claim language is interpreted in light of the specification. Georgia Pacific Corp. v. United States Plywood Corp., 118 USPQ 122 (2d Cir. 1958)

[o]n the other hand, patentable inventions cannot always be described in terms of exact measurements, symbols, and formulae, and the applicant necessarily must use the meager tools provided by language, tools which admittedly lack exactitude and precision. If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more. [emphasis supplied]

Further, A claim need not describe the invention, such description being the role of the disclosure portion of the specification, not the role of the claims. Orthokinetics, Inc. V. Safety Travel Chairs, Inc., 1 USPQ2d 1981, 1088 (Fed. Cir. 1986)).

Turning directly to the Office Action and the text of the indefiniteness rejection made therein, the Examiner's suggested alternative claim language is noted with gratitude. Applicants respectfully decline the suggestion, however, on the basis that it does not describe the invention Applicants wish to claim. The Examiner stated that

...the claims are limited to a determination of the solubility of salts of compounds and comparing each measured solubility with a target solubility. There is no procedure that involves locating one or more salts of a compound in the body of the claim. [Page 2 of Office Action, bottom paragraph].

The Examiner is correct that the claims involve a determination of the solubility of salts of compounds, although the claims are not "limited" to that, i.e., there are other elements in the claims as well. It is respectfully submitted that the Examiner is in error when he states that "[t]here is no procedure that involves locating.....", however. Applicants discuss this point below. Before completing this line of argument, however, Applicants wish to digress for a short discussion relating to the invention so that the Examiner may better understand why Applicants structured their claims as they have.

The invention is based, *inter alia*, on the recognition by Appellant that different salts of a given compound can have different solubilities in the same cyclodextrin. The ability and/or capacity to be able to determine differences in equilibrium solubility between different salts in cyclodextrin solution was very unexpected, conventional wisdom being that there should be no such difference, as explained in the specification at page 2, lines 14-27. That is one reason why Applicants drafted their claims to contain a step of locating or determining a salt based on its solubility in a given cyclodextrin, i.e., because it was not known that different salts would exhibit different solubilities, and obviousness [i.e., patentability] cannot be predicated on what is unknown. In re Naylor, 152 USPQ 106 (CCPA 1967), quoting In re Spoor, 150 USPQ 449 (CCPA 1966). Repeating, but in different words, Applicants' claims do in fact contain a step of determining the equilibrium solubility of salts in a cyclodextrin, and that step helps to confer novelty and unobviousness on Applicants' claims. That is, because the art was not aware that different salts could exhibit different equilibrium solubilities in the same cyclodextrin, it would not have been obvious to do so, as required by Applicants' claims. In this regard, Applicants have carefully studied the Examiner's suggested replacement claim language, but that suggested language appears to place the invention more in the method by which solubility is determined than in the determination itself. The invention does not reside in the manner solubility is determined, however.

The Examiner stated that "There is no procedure that involve locating one or more salts of a compound in the body of a claim." The Examiner further stated that the preamble of claims 1 and 2 fail to correspond in scope with the claimed language

disclosed in claims 1 and 2 because the only substantial disclosed step disclosed in the claims involve determining the solubility of salts. First, the undersigned is unaware of any rule stating that the preamble is required to correspond in scope with the rest of the claim. Second, it is Applicants' position that the claims would be clear and concise to those skilled in the art without further amendment. Third, claim 1 is complete as it stands, it being noted that the claim expresses more than a solubility determination step, and claim 2 expressly contains a selection step in addition to a solubility determination step. Thus, Applicant disagrees with the Examiner's statement that the only substantial step involved is the determination of the salt solubility. It is again emphasized that the ability or capacity to make such a solubility determination was unexpected and surprising.

With reference to the legal requirements for definiteness as reviewed above, claim 1 is clear to those skilled in the art. The claim does indeed express a step whereby determining the equilibrium solubility of salts in cyclodextrin is required, as stated by the Examiner. The claim also requires comparison of each such determined equilibrium solubility with a desired target solubility (i.e., the minimum pre-determined or pre-chosen solubility required for the compound being tested, as defined at page 4, lines 25-26). These two required steps together define the method of locating a salt of a compound having a solubility in a cyclodextrin equal to or greater than a desired target solubility. The skilled person would understand exactly what is required. Although methods for determining the equilibrium solubility are disclosed in Applicants' specification and/or otherwise known in the art, the invention does not reside in the exact solubility determination/measurement method used. It is for that reason that Applicants decline to place that step in the claims.

Claim 2, like claim 1, is complete. It requires a method of determining a useful salt, from within a series of salts of a particular medicinal compound, for use in making a composition comprising the useful salt and a cyclodextrin. The first step requires obtaining the salts. Then the equilibrium solubility in aqueous cyclodextrin solution is determined for each salt. The final step is selecting, **as said useful salt**, a salt from the series which has a solubility in the cyclodextrin solution equal to or greater than a desired target solubility. Thus the claim contains more than the single solubility determination step alleged by the Examiner. Terms have been defined and exemplified in the specification. It is simply unclear to Applicants why the Examiner believes the skilled person would not find claim 2 clear and distinct in view of its logical presentation

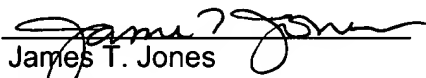
based on Applicants' use of terms that have been defined in the specification. Even though the Examiner did not specifically single out claim 3 as to its preamble, the same argument as that just made for claim 2 applies to claim 3 as well. A number of steps are recited in addition to determining the equilibrium solubility of salts in aqueous cyclodextrin solution. The steps are logically presented, terms are defined, and it is respectfully submitted that those skilled in the art would readily understand the metes and bounds of the property Applicants are claiming.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

Date: November 22, 2002


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